method, Applicants have amended the claims as suggested. Support for these amendments can be found throughout the specification , including Figure 2.

With respect to the lack of a sample preparation step, Applicants have amended the claims to specify that the sample of the instant methods are liquid samples. As taught in the specification at page 22, lines 7-21, the term "bodily fluid and/or extract" meant a substance that is removed from the subject and, when not able to be readily assayed, must be prepared to form a liquid sample. As stated in the specification, such sample preparation is well known in the art. However, to clarify the type of sample that is used in the instant method, the term "liquid sample" is now employed.

Finally, with respect to the Examiner's suggestion that the claims as written do not provide that it is possible that the oligonucleotide of interest is not present in the sample, Applicants respectfully submit that such an understanding is inherent to the present method. Like all such detection methods, if there is a final reading of "zero" or a level that does not exceed background, then one of skill understands that the entity being detected is not present in the sample being assayed. However, Applicants, in an earnest effort to advance the

prosecution, have amended the claims to recite that detection means finding a level of the oligonucleotide that is above the level found in a blank sample, a sample which contains no oligonucleotide.

Withdrawal of this rejection is therefore, respectfully requested.

II. Rejection of Claims Under 35 U.S.C. 112, Second Paragraph

Claims 1-10 and 12 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner suggests that the preamble states a method for detecting and quantitating while the final process step is only for detecting. Applicants have amended the claims to clarify the invention.

The Examiner suggests that claim 12 is of improper dependent form for failing to further limit the subject matter of the previous claim. Applicants have canceled claim 12, therefore this rejection with respect to claim 12 is moot.

The Examiner suggests that claims 1-10 and 12 are indefinite in recitation of "single-stranded and double-stranded oligonucleotide moieties are formed" as it is unclear what a

double-stranded moiety is and then suggests that the term hybrid would be more appropriate. Applicants have amended the claims as suggested by the Examiner.

The Examiner suggests that claims 1-10 and 12 are directed to detecting an oligonucleotide, however, the claim appears to require the presence of an oligonucleotide and will not work when none is present. As discussed *supra*, Applicants have amended the claims to specify that the detection level must exceed the level of a blank sample.

Claims 1-10 and 12 are suggested by the Examiner as being incomplete for omitting essential steps, specifically wash steps. Also as discussed *supra*, Applicants have amended the claims.

Finally, the Examiner suggests that claim 10 is indefinite because "single-strand specific nuclease" lacks proper antecedent basis. Applicants have amended claim 1 to clarify the invention.

Based on each of these amendments to the claims, withdrawal of this rejection is respectfully requested.

III. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly,

favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**VERSION WITH MARKINGS TO SHOW CHANGES MADE**."

Respectfully submitted,

Jane Massey Licata
Registration No. 32,257

Date: **May 3, 2002**

Licata & Tyrrell P.C.
66 E. Main Street
Marlton, New Jersey 08053

(856) 810-1515

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Please cancel claim 12.

The claims have been amended as follows:

1. A method for detecting an oligonucleotide in a ~~bodily fluid or extract~~ liquid sample, consisting of the steps of:

a) contacting ~~said fluid or extract~~ a liquid sample with a probe complementary to an oligonucleotide so that ~~both single-stranded and double-stranded oligonucleotide moieties are formed~~ the probe and an oligonucleotide present in the sample can form hybrid moieties in said ~~fluid or extract~~ sample, wherein said probe comprises a detectable marker and a binding moiety;

b) placing said ~~fluid or extract~~ sample in contact with a solid support to which a binding partner of said binding moiety is attached so that ~~both single-stranded and double-stranded oligonucleotide moieties present~~ said hybrid moieties present in said ~~fluid or extract~~ sample and unhybridized probe will be attached to said solid support;

c) removing any oligonucleotide from said sample that has not formed a hybrid moiety;

~~c~~d) contacting said ~~fluid or extract~~ sample with a single strand specific nuclease under conditions in which probe which is not hybridized to form ~~said double-stranded oligonucleotide moieties~~ hybrid moieties is degraded and thus is no longer attached to said solid support; ~~and~~

e) removing any unbound detectable marker from said sample; and

~~d~~f) detecting a label associated with said marker wherein the presence of said label indicates the presence of said ~~double-stranded oligonucleotide~~ hybrid moieties bound to said solid support wherein detection of said label at levels above the level characteristic of a liquid sample that was prepared as a blank sample to contain no oligonucleotide indicates the presence of said oligonucleotide in said liquid sample.